

6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-5188

August 18, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204



Dear Sirs:

Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug and Cosmetic Act that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Thompson brand name bearing the following statement(s) on the label and/or in the labeling:

<u>Feverfew</u>: [It] promotes healthy blood vessel tone. Feverfew may help regulate many body activities in the maintenance of optimal health. Feverfew contains a compound called parthenolide, which helps to maintain normal protective function of the organs and the skin. The aromatic Feverfew has been used since the Middle Ages. Feverfew contains compounds that help promote healthy blood vessel tone and relax smooth muscle tissue.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

Sincerely,

Deborah Shur Trinker

Vice President of Regulatory Affairs

and Assistant General Counsel

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Enclosure